PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
CD005PCT		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP 03/15641	05.12.2003	05.12.2002
International Patent Classification (IPC) or both national classification and IPC		
A61L27/50, A61L27/58, A61F2/06, A61F2/24		
Applicant		
CARDIO INCORPORATED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 12 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 10 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
17.06.2004	03.02.2005
Name and mailing address of the international preliminary examining authority:	Authorized Officer
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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/JP 03/15641

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-192	as originally filed

Claims, Pages

195, 196, 200, 202, 204	as originally filed
193, 194, 197-199, 201, 203, 205-207	received on 11.10.2003

Drawings, Sheets

1/64-64/64	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 1-102 (partially)

   because:

   ☒ the said international application, or the said claims Nos. 40-48,96-100 relate to the following subject matter which does not require an international preliminary examination (specify):

   see separate sheet

   ☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 1-67,69-102 are so unclear that no meaningful opinion could be formed *(specify)*:

   see separate sheet

   ☒ the claims, or said claims Nos. 1-67,69-102 are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 1-67,69-102

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	68
	No:	Claims	1-67,69-102
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-102
Industrial applicability (IA)	Yes:	Claims	1-39,49-95,101,102
	No:	Claims	

2. Citations and explanations

see separate sheet

Reference is made to the following documents:

D1: US 2002/165601 A1 (CLERC CLAUDE O) 7 November 2002 (2002-11-07)
D2: US-A-5 584 875 (DUHAMEL RAYMOND C ET AL) 17 December 1996 (1996-12-17)
D3: GB-A-2 280 372 (JOHNSON & JOHNSON MEDICAL) 1 February 1995 (1995-02-01)
D4: EP-A-0 636 378 (JOHNSON & JOHNSON MEDICAL) 1 February 1995 (1995-02-01)
D5: EP-A-0 194 192 (ETHNOR) 10 September 1986 (1986-09-10)
D6: US-A-5 741 257 (KIRSCH AXEL) 21 April 1998 (1998-04-21)
D7: US-A-5 948 020 (LEE SEUNG-JIN ET AL) 7 September 1999 (1999-09-07)
D8: WO 01/32229 A (SMITH & NEPHEW ; COTTON NICHOLAS JOHN (GB)) 10 May 2001 (2001-05-10)
D9: US-B-6 319 2641 (PAASIMAA SENJA ET AL) 20 November 2001 (2001-11-20)
D10: HEINO A ET AL: "Application of a self-reinforced polyglycolic acid (SR-PGA) membrane to the closure of an abdominal fascial defect in rats." JOURNAL OF BIOMEDICAL MATERIALS RESEARCH. 1999, vol. 48, no. 5, 1999, pages 596-601, XP002280760 ISSN: 0021-9304
D11: EP-A-0 943 298 (COUSIN BIOTECH S A S) 22 September 1999 (1999-09-22)
D12: WO 93/17635 A (BARD INC C R) 16 September 1993 (1993-09-16)
D13: WO 95/25482 A (ORGANOGENESIS INC) 28 September 1995 (1995-09-28)
D14: EP-A-1 023 879 (MEDTRONIC INC) 2 August 2000 (2000-08-02)

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 40-48,96-100 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article

34(4)(a)(I) PCT).

Those claims that are directed to in vivo implanting and organ regeneration should be strictly limited to non-humans and for non-therapeutical purposes.

The search had been restricted under articles 5 and 6 PCT to the following :

The searched invention:
An implant comprising:
- a first knit layer made of a biodegradable polymer
- a second woven layer made of a biodegradable polymer
Optional features:
- an intermediate biodegradable polymer layer
- a biomolecule attached to the first layer
- and all other technical features that appear in the claims and that are both founded by the description and clear

Further, a process for preparing the implant and a method of culturing the implant inside an non human organism for non therapeutical purposes.

NB: This is NOT a suggestion for an allowable claim. The applicant's charge was to propose claims that are clear and founded on the description, and that enable the skilled person to realise the invention (Art. 5 and 6 PCT).

Claims or parts of claims relating to inventions for which no International Search Report has been established cannot be subject of the International Preliminary Examination (Rule 66.1(e) PCT).

Of the current set of claims, only claim 68 covers the searched invention.
Examination will thus be limited to claim 68 and to the searched invention.

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

V.1 INVENTION

The searched invention:

An implant comprising:
- a first knit layer made of a biodegradable polymer
- a second woven layer made of a biodegradable polymer

Optional features:
- an intermediate biodegradable polymer layer
- a biomolecule attached to the first layer
- and all other technical features that appear in the claims and that are both founded by the description and clear

Further, a process for preparing the implant and a method of culturing the implant inside an non human organism for non therapeutical purposes.

NB: This is NOT a suggestion for an allowable claim. The applicant's charge was to propose claims that are clear and founded on the description, and that enable the skilled person to realise the invention (Art. 5 and 6 PCT).

V.2 CLARITY

The objections made under Art. 5 and 6 in the International Search Report are maintained.

The applicant repeatedly refers to a "medicament" where a "medical device" is intended: see claims 49,50,82-84,101,102.

The current form of the claims, where words added compared to the initial set of claims are underlined and words deleted are put into square brackets is unclear, as it confuses the reader whether the content in brackets is deleted or not.

The applicant should delete all occurences of the relative term 'about', where this term refers to a range or to range limits.
Further the applicant should delete all statements similar to 'incorporated herein by reference'.

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed

in the document D1 is not mentioned in the description, nor is this document identified therein.

V.3 PRIOR ART

If not otherwise specified, subject matter of cited documents relates to the passages indicated in the search report.

D1 - US2002165601
A bioabsorbable stent graft made of a woven, knitted or braided inner (luminal) first layer made of biodegradable polymers (lactide, glycolide, etc.) and a second outer layer that is tighter woven, knitted or braided, made of biodegradable elastomers.
In an alternative, the second layer is made from the same biodegradable material as the first layer, and is woven.
The two layers are secured to each other through adhesive polymer solutions, of which the solvent is evaporated under heat.
No grafting of biomolecules is disclosed.

D2 - US5584875
A vascular graft made of a knitted biostable polymer that is soaked in a albumin or collagen solution (or virtually any biocompatible, bioerodible polymer such as polysaccharides and glycosaminoglycans) that is subsequently crosslinked.
The surface promotes cell ingrowth.

D3 - GB2280372
A composite layered implant comprising a collagen matrix poured onto a woven or knitted fabric made of a biodegradable polymer (such as a copolymer of lactic acid and glycolic acid: VICRYL), where the collagen matrix comprises oil droplets and can comprise a medicament (eg cytokine, growth factor, etc.) and can be optionnaly crosslinked.
The implant is to be used as a vascular prosthesis.

Cites EP0194192.

D4 - EP0636378
A composite layered implant comprising a collagen matrix poured onto a woven or knitted

fabric made of a biodegradable polymer (such as a copolymer of lactic acid and glycolic acid), where the collagen matrix comprises a medicament, can comprise oil droplets and can be optionnaly crosslinked.
The implant is to be used for periodontal disease.

Cites EP0194192.

D5 - EP0194192
A composite layered implant comprising a collagen matrix poured onto a knitted fabric made of a biodegradable polymer (such as a copolymer of lactic acid (10%) and glycolic acid (90%) = VICRYL).
Alternatively, the implant can be made of two identical (knitted) fabrics.
The implant is to be used as a vascular prosthesis.

Cited in EP0636378 and in GB2280372.

D6 - US5741257
A layered bone membrane for healing a recess comprising a plurality of woven or knitted layers of different textures made from biodegradable material such as collagen, polylactide/VICRYL, polylactide.
The specific embodiments describe a membrane made of four woven collagen layers.

D7 - US5948020
An implantable resorbale membrane made of a woven or knitted fabric layer of biodegradable polymers (lactide, glycolide, etc.) and a coating made by applying a coating solution comprising a biodegradable polymer (lactide, glycolide, caprolactone, etc.) and a pore forming agent to the fabric layer.

D8 - WO0132229
A connective tissue implant comprising two layers made by different yarn treating methods, wound into a spiral.
The examples disclose a felt attached to a braided/knitted layer.
The fibers are made of bioabsorbable polymers (PGA,PLA, etc).

D9 - US6319264

A hernia mesh comprising a first layer made of DEXON MESH (knitted PGA fibres, see NLM10490672) and a second layer made of poly(L/D lactide), knitted. The two layers were sown together.
A third optional film layer made of bioabsorbable polymers is positioned on top.

D10 - XP002280760 - NLM10490672
Hernia membrane made of DEXON-MESH (knitted PGA fibres) and a strip of muscle tissue.

D11 - EP0943298
A surgical plate made from a woven or knitted textile made of a non resorbable polymer or a mixture of resorbable and non-resorbable material, an adhesive layer (thermosetting or thermo-curable) and a composite glass-PTFE porous sheet.

Cites WO9317635.

D12 - WO9317635
A prosthesis for limiting postoperative adhesions, comprising a first knitted layer made of biostable or biodegradable (VICRYL) polymers, attached through a silicone adhesive to a barrier layer made of a silicone elastomer sheet or a PTFE mesh.

Cited by EP0943298.

D13 - WO9525482
Implants made of three-dimensional bioabsorbable woven or knitted collagen fibres.

D14 - EP1023879
Prosthetic heart valves made of biostable polymers consisting of a body portion or an underlayer covered by an outer layer of woven or knitted biostable polymer or collagen fibers, where this outer layer is porous and rough to permit cell ingrowth.
Therapeutic agents, mainly to prevent an inflammatory response to the implant, can be included in the body part.
For the body part, a collagen sponge is also envisaged.
Medical devices made from polymers are known to contain therapeutic agents.

V.4 NOVELTY

Remarks under Art. 33(2) PCT

Claim 68 appears to be novel over the prior art.

With respect to the searched invention:
Document D1 anticipates the invention where it has either no optional features or where it has an intermediate biodegradable polymer layer.

V.5 INVENTIVE STEP

Remarks under Art. 33(3) PCT

Document D1, which is considered to represent the most relevant state of the art, discloses a bioabsorbable stent graft made of a knit first layer and a woven second layer where both layers are prepared from the same bidegradable material such as lactide, glycolide, etc. and are secured to each other, from which the subject-matter of claim 68 differs in that the second layer is made of poly(L-lactic acid) and the first layer is made of poly(glycolic acid).

No particular technical effect is achieved through the choice of these particular biodegradable polymers.

The technical effect achieved is (specify for both prior art and claim ... is

The problem to be solved by the present invention may therefore be regarded as to provide a stent graft with an alternative composition.

The solution proposed in claim 68 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

Changing one well-known biodegradable polymer for another, both cited in D1, falls into the scope of normal variation of the skilled person.

With respect to the searched invention:
It appears obvious to provide a collagen coating on the luminal side of a vascular graft

such as a stent of which patency is of mayor interest, given that it is in close contact with blood stream. The skilled person was aware of using collagen to solve this problem, as it is an established solution at least since 1996, the year in which D2 was disclosed and the latter describing the use of collagen for such a purpose.

The invention appears to lack inventive step.

CLAIMS (AMENDMENT UNDER ARTICEL 34)

1. (Amended) A biocompatible implant, comprising:

A) a biological molecule; and

B) a support, wherein the biological molecule is type I collagen.

2. (Cancelled)

3. (Cancelled)

4. (Cancelled)

5. (Cancelled)

6. (Cancelled)

7. (Cancelled)

8. (Cancelled)

9. (Cancelled)

10. (Cancelled)

11. (Amended) A biocompatible implant according to claim 1, wherein the biological molecule further includes [type I collagen or] type IV collagen.

12. (Amended) A biocompatible implant according to claim 1, wherein the biological molecule further includes [collagen and] a cytokine.

13. A biocompatible implant according to claim 1, wherein the support is in the form of a membrane.

14. A biocompatible implant according to claim 1, wherein the support is in the form of a tube.

15. A biocompatible implant according to claim 1, wherein the support is in the form of a valve.

16. A biocompatible implant according to claim 1, wherein the support includes biodegradable polymer.

17. A biocompatible implant according to claim 1, wherein the support includes at least one component selected from the group consisting of poly(glycolic acid) (PGA), poly(L-lactic acid) (PLA) and polycaprolactum (PCLA).

18. A biocompatible implant according to claim 1, wherein the support includes PGLA having a glycolic acid-to-lactic acid ratio of from about 90 : about 10 to about 80 : about 20.

instructions describing usage of the implant,

wherein the instructions describe that the implant is administered to a predetermined site.

38. A medical kit according to claim 37, wherein the predetermined site is selected from the group consisting of vascular endothelium, vascular smooth muscle, elastic fiber, skeletal muscle, cardiac muscle, osteoblast, neuron and collagen fiber.

39. A medical kit according to claim 37, wherein the instructions describe that the biocompatible implant is implanted in such a manner that at least a part of an organ or tissue to be subjected to implantation is left *in situ*.

40. (Amended) A method for treating an injured site of a body, comprising the step of:

A) implanting a biocompatible implant to a part or whole of the injured site,

wherein the biocompatible implant comprises:

A-1) a biological molecule; and

A-2) a support, wherein the biological molecule is type I collagen.

41. A method according to claim 40, wherein in the implanting step, the biocompatible implant is implanted in such a manner that at least a part of an organ or tissue to which the injured site belongs is left *in situ*.

42. A method according to claim 40, further comprising administering a cellular physiologically active substance.

43. A method according to claim 42, wherein the cellular physiologically active substance is selected from the group

consisting of a granulocyte macrophage colony stimulating factor (GM-CSF), a macrophage colony stimulating factor (M-CSF), a granulocyte colony stimulating factors (G-CSF), a multi-CSF (IL-3), a leukemia inhibiting factor (LIF), a c-kit ligand (SCF), an immunoglobulin family member, CD2, CD4, CD8, CD44, collagen, elastin, proteoglycan, glycosaminoglycan, fibronectin, laminin, syndecan, aggrecan, an integrin family member, integrin α chain, integrin β chain, fibronectin, laminin, vitronectin, selectin, cadherin, ICM1, ICAM2, VCAM1, platelet derived growth factor (PDGF), epidermal growth factor (EGF), fibroblast growth factor (FGF), hepatocyte growth factor (HGF) and vascular endothelial growth factor (VEGF), and polypeptides and peptides related thereto..

44. A method according to claim 40, further comprising performing a treatment for suppressing an immune reaction.

45. (Amended) A method for reinforcing an organ or tissue in a body, comprising the step of:

A) implanting a biocompatible implant to a part or whole of the organ or tissue,

wherein the biocompatible implant comprises:

A-1) a biological molecule; and

A-2) a support, wherein the biological molecule is type I collagen.

46. A method for producing or regenerating an organ or tissue, comprising the steps of:

A) implanting a biocompatible implant to a part or whole of the organ or tissue within an organism containing the organ or tissue,

wherein the biocompatible implant comprises:

A-1) a biological molecule; and

A-2) a support, wherein the biological molecule is type I collagen; and

B) culturing the organ or tissue within the organism.

47. Use of a biocompatible implant according to claim 1 for treatment of an injured site within a body.

48. Use of a biocompatible implant according to claim 1 for reinforcement of an organ or tissue within a body.

49. Use of a biocompatible implant according to claim 1 for production of a medicament for treatment of an injured site within a body.

50. Use of a biocompatible implant according to claim 1 for production of a medicament for reinforcement of an organ or tissue within a body.

51. (Amended) A biocompatible tissue support, comprising:

A) a first layer having a rough surface; and

B) a second layer having a strength which allows the second layer to resist *in vivo* impact,

wherein the first layer is attached to the second layer via at least one point[.], wherein the first layer is a knit, and wherein the second layer is a woven.

52. (Cancelled)

53. (Cancelled)

54. A support according to claim 51, wherein the rough

64. A support according to claim 51, wherein the second layer includes at least one component selected from the group consisting of poly(glycolic acid) (PGA), poly(L-lactic acid)(PLA) and polycaprolactum (PCLA), and a copolymer thereof.

65. A support according to claim 51, wherein the second layer includes PGLA having a glycolic acid-to-lactic acid ratio of from about 90 : about 10 to about 80 : about 20.

66. A support according to claim 51, wherein the second layer includes poly(L-lactic acid).

67. (Cancelled)

68. A support according to claim 51, wherein the second layer is a woven of poly(L-lactic acid) and the first layer is a knit of poly(glycolic acid).

69. A support according to claim 51, wherein the attachment is carried out by:

C) an intermediate layer for attaching the first layer with the second layer.

70. A support according to claim 69, wherein the intermediate layer is made of a synthetic biological absorbable polymer.

71. A support according to claim 69, wherein the intermediate layer includes a homopolymer containing a single monomer selected from the group consisting of lactic acid (lactid), glycolide and ε-caprolactam or a copolymer containing two or more monomers therefrom.

comprising a cell.

82. A medicament according to claim 80, for use in implantation into a body.

83. A medicament according to claim 80, wherein a site of the body into which the biological implant is implanted is selected from the group consisting of cardiac valve, blood vessel, pericardium, cardiac septum, intracardiac conduit, extracardiac conduit, dura mater, skin, bone, soft tissue and trachea.

84. A medicament according to claim 80, wherein the biocompatible implant is derived from an organism undergoing the implantation.

85. (Amended) A method for producing a biocompatible tissue support, wherein the biocompatible tissue support comprises:

A) a first layer having a rough surface; and

B) a second layer having a strength which allows the second layer to resist *in vivo* impact,

wherein the first layer is attached to the second layer via at least one point, wherein the first layer is a knit, and wherein the second layer is a woven, and

the method comprises the step of:

attaching the first layer with the second layer.

86. A method according to claim 85, wherein the biocompatible tissue support further comprises:

C) an intermediate layer for attaching the first layer with the second layer,

the attaching step comprises:

a) providing the intermediate layer between

91. A method according to claim 90, wherein the attaching step comprises crosslinking treatment.

92. A method according to claim 90, wherein the biological molecule is collagen, and the attaching step comprises collagen crosslinking treatment.

93. A method according to claim 86, wherein the intermediate layer is produced by casting a film material onto a glass plate, followed by air drying, to form a film.

94. A method according to claim 86, wherein the step b) comprises exerting a pressure of at least about 0.1 g/cm^2 onto the support.

95. A method according to claim 86, wherein the step b) comprises exerting a pressure of at least about 0.5 g/cm^2 onto the support.

96. (Amended) A method for treating an injured site of a body, comprising the step of:

A) implanting a biocompatible tissue support to a part or whole of the injured site,

wherein the biocompatible tissue support comprises:

A-1) a first layer having a rough surface; and

A-2) a second layer having a strength which allows the second layer to resist *in vivo* impact,

wherein the first layer is attached to the second layer via at least one point[.] <u>wherein the first layer is a knit, and wherein the second layer is a woven.</u>

97. (Amended) A method for reinforcing an organ or tissue within a body, comprising the step of:

A) implanting a biocompatible tissue support to a

part or whole of the injured site,

wherein the biocompatible tissue support comprises:

A-1) a first layer having a rough surface; and

A-2) a second layer having a strength which allows the second layer to resist *in vivo* impact,

wherein the first layer is attached to the second layer via at least one point[.] wherein the first layer is a knit, and wherein the second layer is a woven.

98. (Amended) A method for producing or regenerating an organ or tissue, comprising the steps of:

A) implanting a biocompatible tissue support to a part or whole of the organ or tissue within an organism containing the organ or tissue,

wherein the biocompatible tissue support comprises:

A-1) a first layer having a rough surface; and

A-2) a second layer having a strength which allows the second layer to resist *in vivo* impact,

wherein the first layer is attached to the second layer via at least one point wherein the first layer is a knit, and wherein the second layer is a woven; and

B) culturing the organ or tissue in the organism.

99. (Amended) Use of a biocompatible tissue support for treatment of an injured site within a body, wherein

the biocompatible tissue support comprises:

A-1) a first layer having a rough surface; and

A-2) a second layer having a strength which allows the second layer to resist *in vivo* impact,

wherein the first layer is attached to the second layer via at least one point wherein the first layer is a knit, and wherein the second layer is a woven.

100. (Amended) Use of a biocompatible tissue support for reinforcement of an organ or tissue within a body, wherein

the biocompatible tissue support comprises:

A-1) a first layer having a rough surface; and

A-2) a second layer having a strength which allows the second layer to resist *in vivo* impact,

wherein the first layer is attached to the second layer via at least one point wherein the first layer is a knit, and wherein the second layer is a woven.

101. (Amended) Use of a biocompatible tissue support for production of a medicament for treatment of an injured site within a body, wherein

the biocompatible tissue support comprises:

A-1) a first layer having a rough surface; and

A-2) a second layer having a strength which allows the second layer to resist *in vivo* impact,

wherein the first layer is attached to the second layer via at least one point wherein the first layer is a knit, and wherein the second layer is a woven.

102. (Amended) Use of a biocompatible tissue support for production of a medicament for reinforcement of an organ or tissue within a body, wherein

the biocompatible tissue support comprises:

A-1) a first layer having a rough surface; and

A-2) a second layer having a strength which allows the second layer to resist *in vivo* impact,

wherein the first layer is attached to the second layer via at least one point wherein the first layer is a knit, and wherein the second layer is a woven.